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10/538,745	06/14/2005	Gordon Feingold	P149-US-01	4284

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DAKO, GLOBAL INTELLECTUAL PROPERTY  
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EXAMINER

BARBEE, MANUEL L

ART UNIT	PAPER NUMBER
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2857

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

## Office Action Summary

Application No.

10/538,745

Applicant(s)

FEINGOLD ET AL.

Examiner

Manuel L. Barbee

Art Unit

2857

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 185-298 is/are pending in the application.
- 4a) Of the above claim(s) 185-248 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 261 and 286 is/are allowed.
- 6) ☒ Claim(s) 249-260, 262-285 and 287-298 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/14/05; 10/13/06; 11/7/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of claims 249-298 in the reply filed on 7 November 2006 is acknowledged. The traversal is on the ground(s) that all claims in the present application are drawn to a group of inventions linked by a single general inventive concept such as using computerized electronic systems and methods to track and facilitate processing of biological samples. This is not found persuasive because the limitations for the special technical feature of a first and second host, in claims 185 and 215 and generally for a server and a database found in claims 216-248 are not found in claims 249-298. The special technical feature of claims 185-248 is directed to remote communication rather than to automated sampling as shown in claims 249-298.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 185-248 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7 November 2006.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 7 November 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. No copies of the three

foreign patent documents on page 2 of the information disclosure statement were received, and these documents were not considered.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 263, 268, 270, 288, 293 and 295 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,289,385 to Grandone (Grandone).

With regard to an automated sample processing system using robotic sample process functions and scheduling a plurality of sample process operations, as shown in claims 263 and 288, Grandone teaches a biological sample analyzer with robotic pipette-booms and scheduling sample operations (col. 5, line 66 - col. 6, line 36; col. 7, lines 36-58; col. 10, lines 18-53). With regard to capturing and storing important details of process operations, as shown in claims 263 and 288, Grandone teaches outputting data analysis results to data storage (col. 7, lines 40-58). With regard to a plurality of scheduled sample process operations, as shown in claims 263 and 288, Grandone teaches more than one scheduled operation (col. 10, line 18 - col. 11, line 10). With regard to accepting a prompt from a user to display important details and providing information to at least one person, as shown in claims 263 and 288, Grandone teaches allowing an user to enter a load list for samples and operations to be performed (col. 9, lines 3-22; col. 7, lines 40-58).

With regard to storing individual operation data, as shown in claims 268 and 293, Grandone teaches storing results (col. 7, lines 40-58).

With regard to displaying at least a portion of the information, as shown in claims 270 and 295, Grandone teaches printing test results (col. 7, lines 40-58).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 249-251 and 274-276 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of US Patent No. 5,473,551 to Sato et al. (Sato) and US Patent Application Publication 2005/0250211 to Reinhardt et al. (Reinhardt).

With regard to an automated sample processing system using robotic sample process functions and scheduling a plurality of sample process operations, as shown in claims 249 and 274, Grandone teaches a biological sample analyzer with robotic pipette-booms and scheduling sample operations (col. 5, line 66 - col. 6, line 36; col. 7, lines 36-58; col. 10, lines 18-53). With regard to capturing and storing important details of process operations, as shown in claims 249 and 274, Grandone teaches outputting data analysis results to data storage (col. 7, lines 40-58). With regard to a plurality of scheduled sample process operations, as shown in claims 249 and 274, Grandone teaches more than one scheduled operation (col. 10, line 18 - col. 11, line 10).

Grandone does not teach monitoring replenishable supply information and automatically notifying at least one person of a need for a replenishable supply, as shown in claims 249 and 274. Sato teaches monitoring whether a part needs to be exchanged or updated and displaying an alarm to notify an user of the need for an update or for part replacement (col. 2, line 30 - col. 4, line 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include monitoring parts that need to be updated, as taught by Sato, because then worn parts causing inaccurate measurements would not have been used (Sato, col. 1, line 65 - col. 2, line 56).

Grandone does not teach replenishing the replenishable supply concurrently with sample processing, as shown in claims 249 and 274. Reinhardt teaches that reagents can be delivered to workstation while replacing or replenishing reagents to the system (pars. 17, 45, 96). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include replenishing reagents, as taught by Reinhardt, because then throughput would have been increased (Reinhardt, par. 9).

Grandone does not teach advance notifying at least one person in response to monitoring, as shown in claims 250 and 275. Sato teaches displaying an alarm to notify an user of the need for an update or for part replacement (col. 2, line 30 - col. 4, line 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include monitoring parts that need to be updated, as taught by Sato, because then worn parts causing

inaccurate measurements would not have been used (Sato, col. 1, line 65 - col. 2, line 56).

Grandone does not teach monitoring the specific supplies shown in claims 251 and 276. Reinhardt teaches that reagents can be delivered to workstation while replacing or replenishing reagents to the system (pars. 17, 45, 96). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include replenishing reagents, as taught by Reinhardt, because then throughput would have been increased (Reinhardt, par. 9).

8. Claims 252-257 and 277-282 rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of US Patent Application Publication 2003/0200111 to Damji (Damji).

With regard to an automated sample processing system using robotic sample process functions and scheduling a plurality of sample process operations, as shown in claims 252 and 277, Grandone teaches a biological sample analyzer with robotic pipette-booms and scheduling sample operations (col. 5, line 66 - col. 6, line 36; col. 7, lines 36-58; col. 10, lines 18-53). With regard to capturing and storing important details of process operations, as shown in claims 252 and 277, Grandone teaches outputting data analysis results to data storage (col. 7, lines 40-58). With regard to a plurality of scheduled sample process operations, as shown in claims 252 and 277, Grandone teaches more than one scheduled operation (col. 10, line 18 - col. 11, line 10).

Grandone does not teach monitoring historical usage information and advance notifying at least one person, as shown in claims 252 and 277. Damji teaches

Art Unit: 2857

monitoring the historical usage of materials and allowing an user to order based on the historical information (par. 54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include monitoring historical usage, as taught by Damji, because then supply chains would have been more efficient (Damji, pars. 2-4).

Grandone does not teach monitoring user statistical information, as shown in claims 253 and 278. Damji teaches monitoring which sizes are most commonly used (par. 54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include monitoring statistical data, as taught by Damji, because then supply chains would have been more efficient (Damji, pars. 2-4).

Grandone does not teach notifying at least one person of a predictive need, monitoring predictive usage information, or utilizing order lead time information, as shown in claims 254-256 and 279-281, and notifying an operator, as shown in claims 257 and 282. Damji teaches monitoring the historical usage of materials and allowing an user to order based on the historical information (par. 54). The historical information is a prediction of usage. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include monitoring historical usage, as taught by Damji, because then supply chains would have been more efficient (Damji, pars. 2-4).



9. Claims 258, 259, 262, 269, 271, 283, 284, 287, 294 and 296 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of US Patent Application Publication 2003/0163031 to Madden et al. (Madden).

With regard to an automated sample processing system using robotic sample process functions and scheduling a plurality of sample process operations, as shown in claims 258 and 283, Grandone teaches a biological sample analyzer with robotic pipette-booms and scheduling sample operations (col. 5, line 66 - col. 6, line 36; col. 7, lines 36-58; col. 10, lines 18-53). With regard to capturing and storing important details of process operations, as shown in claims 258 and 283, Grandone teaches outputting data analysis results to data storage (col. 7, lines 40-58). With regard to a plurality of scheduled sample process operations, as shown in claims 254 and 283, Grandone teaches more than one scheduled operation (col. 10, line 18 - col. 11, line 10).

Grandone does not teach establishing a network and accepting a prompt from a user to establish a remote access connection between the slide processing network and a remote location and to display at least a portion of the important details of the sample process operations at the remote location, as shown in claims 258 and 283. Madden teaches using a network to transfer sample results to a database that is accessible to remote users (pars. 19, 30 and 32). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include a remote network connection for transferring data, as taught by Madden, because then analysis of results by other professionals would have been facilitated (Madden, pars. 2-9).

Grandone does not teach connecting remotely to a laboratory information system, as shown in claims 259 and 284. Madden teaches using a network to transfer sample results to a database that is accessible to remote users (pars. 19, 30 and 32). The ability to transmit the data requires a computer or information system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include a remote network connection for transferring data, as taught by Madden, because then analysis of results by other professionals would have been facilitated (Madden, pars. 2-9).

With regard to an automated sample processing system using robotic sample process functions and scheduling a plurality of sample process operations, as shown in claims 262 and 287, Grandone teaches a biological sample analyzer with robotic pipette-booms and scheduling sample operations (col. 5, line 66 - col. 6, line 36; col. 7, lines 36-58; col. 10, lines 18-53). With regard to capturing and storing important details of process operations, as shown in claims 262 and 287, Grandone teaches outputting data analysis results to data storage (col. 7, lines 40-58). With regard to a plurality of scheduled sample process operations, as shown in claims 262 and 287, Grandone teaches more than one scheduled operation (col. 10, line 18 - col. 11, line 10). With regard to accepting a prompt from a user to display important details and providing information to at least one person, as shown in claims 262 and 287, Grandone teaches allowing an user to enter a load list for samples and operations to be performed (col. 9, lines 3-22; col. 7, lines 40-58).

Grandone does not teach storing details as unmanipulatable, as shown in claims 262 and 287. Madden teaches storing data as “read-only” (par. 27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to store data in “read-only” format, as taught by Madden, because then data would not have been accidentally when being viewed.

Grandone teaches all the limitations of claim 263 upon which claim 269 depends and claim 288 upon which claim 294 depends. Grandone does not teach creating the specific records shown in claims 269 and 294. Madden teaches storing data as “read-only” (par. 27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to store data in “read-only” format, as taught by Madden, because then data would not have been accidentally when being viewed.

Grandone teaches all the limitations of claim 270 upon which claim 271 depends and claim 295 upon which claim 296 depends. Grandone does not teach displaying information specifically as shown in claims 271 and 296. Madden teaches remotely displaying information (pars. 19, 30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include a remote network connection for transferring data, as taught by Madden, because then analysis of results by other professionals would have been facilitated (Madden, pars. 2-9).

Art Unit: 2857

10. Claims 260 and 285 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of Madden as applied to claims 258 and 283 above, and further in view of US Patent Application Publication 2004/0220745 to Hosomi (Hosomi).

Grandone and Madden teach all the limitations of claim 258 upon which claim 260 depends and claim 283 upon which claim 285 depends. Grandone and Madden do not teach remote access to a manufacturer, supplier or maintenance personnel locations, as shown in claims 260 and 285. Hosomi teaches a network connection to an instrument supplier (pars. 25 and 32). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer combination, as taught by Grandone and Madden, to include a remote connection a manufacturer and supplier such as a instrument provider, as taught by Hosomi, because then supplies would have been replaced more quickly (Hosomi, pars. 3, 4).

11. Claims 264 and 289 rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of US Patent Application Publication 2003/0032048 to Kim et al. (Kim).

Grandone teaches all the limitations of claim 263 upon which claim 264 depends and claim 288 upon which claim 289 depends. Grandone does not teach sequential playback capability, as shown in claims 264 and 289. Kim teaches playing back the movement in a cell migration system (par. 215, 216). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include playback, as taught by Kim, because then analyzer steps could have been observed in real-time at a later time.

12. Claims 265-267 and 290-292 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of Kim as applied to claims 264 and 289 above, and further in view of US Patent No. 4,139,867 to Foerster (Foerster).

Grandone and Kim teach all the limitations of claim 264 upon which claims 265-267 depend and claim 289 upon which claims 290-292 depend. Grandone and Kim do not teach altering the speed of playback, as shown in claims 265-267 and 290-292. Foerster teaches altering the speed of video playback (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer combination, as taught by Grandone and Kim, to include playback with altered speed, as taught by Foerster, because then the user would have been able to slow down the playback for better observation.

13. Claims 272, 273, 297 and 298 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of Madden as applied to claims 271 and 296 above, and further in view of Kim.

Grandone and Madden teach all the limitations of claim 271 upon which claims 272 and 273 depend and claim 296 upon which claims 297 and 298 depend. Further with regard to a plurality of automated slide stainers and connecting the stainers, as shown in claims 273 and 298, Madden teaches a network for use with staining equipment (pars. 30-33). Grandone and Madden do not teach real time displaying of individual slide log data, as shown in claims 272 and 297. Kim teaches real-time playback of cell migration movement (par. 215). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer

Art Unit: 2857

combination, as taught by Grandone and Madden, to include playback, as taught by Kim, because then analyzer steps could have been observed in real-time at a later time.

***Allowable Subject Matter***

14. Claims 261 and 286 are allowed.

15. The following is a statement of reasons for the indication of allowable subject matter: The cited prior art does not teach an automated sample processing method or system that includes processing a biological sample arranged on a slide using robotic functions, scheduling a plurality of sample process operations, storing important details of the operations, accepting a prompt from a user to display at least a portion of the important details, providing information to at least one person, storing time of occurrence data, storing substance identifier data, storing individual robotic movement data, storing subject sample data and storing type of protocol data, as shown in claims 261 and 286.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel L. Barbee whose telephone number is 571-272-2212. The examiner can normally be reached on Monday-Friday from 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on 571-272-2216. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 2857

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Manuel L. Barbee  
Examiner  
Art Unit 2857

mlb  
December 23, 2006